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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/718,034

11/19/2003

Uri Herzberg

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EXAMINER

CLAYTOR, DEIRDRE RENEE

ART UNIT

PAPER NUMBER

1617

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/718,034	Applicant(s) HERZBERG ET AL.	
	Examiner Renee Claytor	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6,25-57 and 59-63 is/are pending in the application.
- 4a) Of the above claim(s) 1-6,25-42,53-57 and 59 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 43-52, 60-63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's response filed on 2/2/2008 is acknowledged.

Applicant's arguments over the 35 USC 112, first paragraph rejection have been fully considered and are found persuasive. Accordingly, the rejection is hereby withdrawn.

Applicant's argue over the 35 USC 102(e) rejection over Kyle that the priority application (60/411,084) does not teach that VR1 antagonists in general are useful in the treatment of addictive disorders. Applicants point to the teaching that the compounds of the invention treat addictive disorders by inhibiting mGluR1 function.

In response to the above argument, it is noted that the priority document teaches that Thiadiazolepiperazine compounds antagonize different receptors or receptor subtypes. Among the receptors that the compounds are taught to antagonize include VR1 receptors, meaning that the compounds are considered as VR1 antagonists. Regardless of the mechanism of action, it is also taught that the compounds treat addictive disorders. Accordingly, the priority document does disclose that a VR1 antagonist treats addictive disorders.

Applicant's arguments over the 35 USC 103 rejection have been considered. Applicants refer back to the previous Office Action in which the 35 USC rejection over Kyle in view of Bakthavatchalam (US Patent 7,074,799) was withdrawn because the patent was commonly assigned with the present application. Applicants assert that that the rejection was improperly used and should be withdrawn.

It is noted that the rejection in the last Office Action was not over Bakthavatchalam (US Patent 7,074,799) but over Bakthavatchalam (US Patent 6,723,730). There is no clear indication that the reference and the present application were commonly owned at the time of the present invention. Accordingly, the rejection is maintained.

Claim Rejections – 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 43-45 and 48-50 rejected under 35 U.S.C. 102(e) as being anticipated by Kyle et al. (US Patent 6,974,818).

Kyle et al. teach compounds that inhibit vanilloid receptor 1 (VR1) function in a cell (Col. 12, lines 19-22). These compounds are administered to animals of need of treatment for addictive disorders, including opioid dependence (Col. 5, lines 19-30, Col. 31, lines 18-25 and Col. 32, line 32). Example 6 outlines a study proving that the compounds of the Kyle et al. invention are capable of decreasing morphine self-administration (thereby inhibiting tolerance), which is a model for an addictive disorder.

Claim Rejections – 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 46-47, 51-52 and 60-63 rejected under 35 U.S.C. 103(a) as being unpatentable over Kyle et al. (US Patent 6,974,818) as applied to claims 43-45 and 48-50 in the above rejection, in view of Bakthavatchalam et al. (US Patent 6,723,730).

Bakthavatchalam et al. teach VR1 antagonists that exhibit K_i values less than 1 micromolar and 100 nanomolar (Col. 17, lines 30-38). Further Bakthavatchalam et al. teach various VR1 receptor antagonists that are multi-aryl (see Table III).

Accordingly, it would be obvious to a person of skill in the art to combine the inventions of Kyle et al. which teach that compounds that inhibit the VR1 receptor are effective in inhibiting the development of tolerance to narcotic analgesics, namely morphine, with the invention of Bakthavatchalam et al. which teach various VR1 antagonists with the claimed K_i values and compounds that are multi-aryl. One would be motivated to combine the prior art references because it is taught by Kyle et al. that VR1 antagonists are useful in treating addictive disorders and because Bakthavatchalam et al. teach VR1 antagonists, one would reasonably expect the same result of inhibition of tolerance to narcotic analgesics.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Claytor whose telephone number is (571)272-8394. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1617

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Renee Claytor

/SREENI PADMANABHAN/
Supervisory Patent Examiner, Art Unit 1617